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| EXAMINER | |
|---|---|
| WESSENDORF, TERESA D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1639 | |

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/665,721 | BELCHER ET AL. | |
| | Examiner | Art Unit | |
| | T. D. Wessendorf | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *13 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *144-157* is/are pending in the application.

4a) Of the above claim(s) *154-157* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *144-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Newly submitted claims 154-157 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims that are drawn to a method of making the composition have been withdrawn from consideration as being a non-elected invention in the restriction/election requirement made on 6/9/2005.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 154-157 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Status of Claims*

Claims 144-157 are pending.

Claims 1-143 have been cancelled.

Claims 154-157 are withdrawn from consideration by original presentation, as stated above.

Claims 144-153 are under examination.

***Withdrawn Objection and Rejection***

In view of the amendments to the claims and applicants' arguments, the following objection and rejections are withdrawn: The objection to the specification for lack of proper antecedent basis; the 35 USC 112, second paragraph rejection; the 35 USC 102(a) over Sagakuchi, Naik and Puentes and 102(b) over Whaley.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 144-153, newly presented, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of

relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004).

The specification fails to provide an adequate written description of a composition comprising a metal nanoparticle bound to a synthetic peptide or a synthetic protein which selectively binds to the metal nanoparticle. The specification, for example, describes synthetic peptide of defined structure to enable its selectivity binding to a specific metal nanoparticle. The disclosure at pages 39-56 describes, "….studies showed that the peptides ***selected using phage display screening possessed specific binding towards Co and not towards other materials***. It

is this specificity that can be used to direct metal materials formation, including magnetic materials..." (Emphasis added.) These studies show that no a priori correlation can be made for a single species of metal material and/or synthetic peptide or protein to another species, let alone, to the huge scope of the claimed genus. The specification does not further describe a composition comprising a macromolecular synthetic protein i.e., more than 100 amino acid residues bound to a metal nanoparticles. The specification, as referred to by applicants, gives a single general statement of a protein. In biotechnological invention one cannot necessarily claim a genus after only describing a single species because there may be uncertainty in the results obtained from species other than those specifically described. This is evident from the Examples in the instant specification, as stated above. See University of California v. Eli Lilly, 43 USPQ 2d 1398, 1405 (1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

***Double Patenting***

Claim 144, for example, is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 37, for example of copending Application No. 10/157,775 ('775 application) or claim e.g., 78 0f copending application 10/155,883 ('883 application) or of claims e.g., 52, 63 and 64, of copending Application No. 10/158,596 ('596). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented and reiterated below. [Note due to the excessive number of claims only the base claim in each applications are cited in the rejection.]

Each of the applications is drawn to nearly identical composition. The instant invention claims a metal binding molecule-synthesized metal particles which is nearly identical to the composition of e.g., '775 application. The '775 application directly recites a composition comprising a metal and binding molecule, as the bacteriophage library. Although each of the claims is worded differently, however, as evident from each of these applications' disclosure the same composition i.e., library of phage and metal is disclosed and described in all of the copending applications.

***Response to Arguments***

Applicants requested holding this rejection under abeyance until an allowable subject matter is found in one of the numerous pending applications.

In reply, since applicants have not set a clear demarcation line among these applications, the double patenting rejection is maintained.

***Double Patenting (Obviousness-type)***

Claim 144, for example, is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 37 of copending Application No. 10/1557,775 or claim 78, for example, of copending application No. 10/155,883 or of claims e.g., 52, 63 and 64, inter alia, of copending Application No. 10/158,596. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons stated above under the 101 double patenting rejection. Furthermore, the form assumes by each of the different compositions do not make the composition different from one another as the compounds in the composition is same. To make a composition in different forms would be an obvious design.

Note the arguments of applicants above under the double patenting rejection and the response therein.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 144, 146 and 148-149, newly presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Kresse et al (6,048,515).

Kresse discloses at e.g., col. 15, line 3 up to col. 16, line 61, including Table 2 and the claims at col. 37, a composition comprising peptides that have an affinity for the iron core (nanoparticle metal, as claimed). The preferred peptides contain the RRTVKHHVN or RRSRHH or RSKRGR sequence or parts thereof in their molecule [one-letter code of amino acids). The peptides have been selected from peptide libraries using biochemical methods (synthetic peptides, as claimed).

Accordingly, the specific compositions of Kresse containing the specific metal components and synthetic peptides fully meet the claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure.

Claims 144, 146 and 147-148, newly presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Lawton et al (USP 5,985,353).

The claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure is fully met by the specific composition of Lawton disclosed at col. 3, line 35 up to col. 6, line 2.

Claims 144, 146 and 148-149, newly presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Josephson et al (Bioconjugate Chem.).

The claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure is fully met by the specific composition of Josephson at e.g., page 188, col. 1, RESULTS and DISCUSSION section.

Claims 144-146 and 150-153, as newly presented, are rejected under 35 U.S.C. 102(e) as being anticipated by Mayes et al (USP 6,713,173).

The claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure is fully met by the specific composition of Mayes et al disclosed at col.2, line 57 up to col. 6, Example 4.

Claims 144-147, as newly presented, are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al (Science).

The claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure is fully met by the specific composition of Lee comprising of ZnS and phage or a peptide with ZnS as disclosed at e.g., page 892, col.2 up to page 895, col. 3 and Example 4, number 7.

Claims 144, 145 and 150, as newly presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Mattoussi et al (J. Am. Chem. Soc.).

The claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure is fully met by the specific composition of Mattoussi et al comprising of Cdse-Zns and bioactive proteins disclosed at e.g., page 12143 up to page 12114.

Claims 144, 146 and 152, as newly presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (Nature Biotechbology).

Brown discloses at page 269 up to page 272, particularly the Discussion and Experimental sections, a composition comprising of proteins bound to metal surfaces. Brown discloses repeating polypeptides able to bind to metallic gold or chromium. The peptides were selected from a population of approximately 5 million different polypeptides (i.e., a synthetic peptide, as claimed). The specific composition of Brown fully meets the broad claimed composition comprising broadly a nanoparticle metal and synthetic peptides of undefined structure.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 144-153, as newly presented, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaguchi et al (Letters to Nature) for reasons set forth in the last Office action and as reiterated below.

Sakaguchi discloses a magnetite particles synthesize from bacteria. See e.g., page 47 up to page 48. Sakaguchi does not teach that the protein containing the magnetite particles is synthetic. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a synthetic protein from the natural protein of Sakaguchi using known synthetic methods. One having ordinary skill in the art would have been motivated to use a synthetic protein in the composition of Sakaguchi for ease of manufacturing said synthetic proteins.

***Response to Arguments***

Applicants recognize that Sakaguchi teaches using RS-I bacteria to form metal oxide particles. But state that Sakaguchi does not teach or suggest that the bacteria contains the claimed synthetic peptide or protein which selectively binds to the metal nanoparticle.

In reply, it is immaterial whether the protein disclosed by Sakaguchi is a natural as opposed to a synthetic one, as claimed. The same composition is being claimed and there is no qualifying features of the instant claimed peptide that differentiates said synthetic peptide from Sakaguchi's natural protein.

Claims 144-153, as newly presented, are rejected under 35 U.S.C. 103(a) as being unpatentable over Warne et al (IEE Transactions) for reasons set forth in the last Office action and reiterated below.

Warne discloses at page 3009 up to 3011 a metal (Co) synthesized metal particles.

***Response to Arguments***

Applicants state that Warne teaches using protein shells prepared from native ferritin to form metal grains

inside the shells. Warne discloses that the empty protein is merely used as a reaction vessel. Thus, the protein of Warne is not a synthetic protein which selectively binds to the metal nanoparticle. Warne also states that the empty protein shell prepared from ferritin could be used to synthesize non-metal nanoparticles, such as cadmium sulfide semiconductor nanoparticles. Therefore, this is clear evidence that the protein shell does not selectively bind to metal nanoparticles, because the protein shell can be used to form metal as well as non-metal nanoparticles. Therefore, Warne does not teach or suggest a metal nanoparticle bound to a synthetic peptide or protein which selectively binds to the metal nanoparticle, as recited in claim 144.

In reply, see the response under Sakaguchi above. Furthermore, whether the protein of Warne binds also to non-metal nanoparticles is immaterial as Warne positively teaches its binding selectively to metal nanoparticles. There is nothing in the claims that recite whether in fact any metal nanoparticles and a peptide or protein of no defined structures achieve the selectivity binding function of the metal to the peptide or protein. Since the claimed composition is known, whether one component of the composition, peptide/protein is synthetic is immaterial to a known composition comprising the

same components. It would have been within the ordinary skill in the art at the time the invention was made to make a synthetic peptide from the natural one using known synthetic method. Peptide synthesis had markedly advanced that it is now automated. Applicants have not provided any evidence of new and unexpected results of a composition containing a synthetic compound. In the absence of new and unexpected results, the claimed composition is prima facie obvious to one having ordinary skill in the art at the time the invention was made.

No claim is allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 154-157 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

April 14, 2006